

Amendment and Response

Applicant: Jeffrey W. Chambers

Serial No.: 10/812,250

Filed: March 29, 2004

Docket No.: C364,105,101

Title: STENT POSITIONING SYSTEM AND METHOD

REMARKS

The following remarks are made in response to the Non-Final Office Action mailed January 8, 2007, in which a Restriction Requirement was set forth relative to the Examiner-identified inventions of Invention I (claims 1-27) and Invention II (claims 28-40), and a provisional election of Invention II was indicated; claims 31 and 34 were rejected under 35 U.S.C. §112, second paragraph; claims 28, 30-32, and 35-40 were rejected under 35 U.S.C. §102(b) as being anticipated by Lam, U.S. Patent No. 5,607,444 ("Lam"); claims 28-30 and 32-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brown et al., U.S. Patent No. 6,093,199 ("Brown") in view of VanTassel et al., U.S. Patent No. 6,652,555 ("VanTassel").

With this Response, claim 13 has been canceled; claim 41 added; and claims 28, 31, 34, and 35 have been amended. Claims 1-12 and 14-41 remain pending in the application and are presented for consideration and allowance.

Restriction Requirement

Applicant confirms the telephonic, provisional election of Invention II (claims 28-40). Further, the restriction requirement is traversed as follows. The Office Action states that the product as claimed (Invention I) "can be used in a materially different method that does not deploy a stent, but a graft or tracheal tube." Applicant respectfully submits that this is not a viable example. Claim 1 (Invention I) is specifically directed toward a stent placement system, and recites a deployment site locator adapted for use with a stent delivery device capable of delivering a stent. Further, claim 2 (Invention I) specifically recites a stent. Further, nothing in the language of Invention I, as claimed, supports a conclusion that a graft or tracheal tube is deployed with the system of Invention I. In the absence of a viable example in accordance with MPEP 806.05(h), it is respectfully requested that the Restriction Requirement be withdrawn and claims 1-12 and 14-27 be examined.

35 U.S.C. §112, Second Paragraph, Rejections

Claim 31 has been amended to depend from claim 30, thus addressing the antecedent basis concern raised by the Examiner.

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Claim 34 has been amended to replace “artery” with “vessel,” thus addressing the antecedent basis concern raised by the Examiner. Though not rejected under §112, second paragraph, a similar amendment has been made to claim 35.

By the above amendments, it is respectfully requested that the §112, second paragraph, rejections be withdrawn.

35 U.S.C. §§102, 103 Rejections

Amended claim 28 relates to a method of deploying an intravascular stent to a patient and includes determining a position of an ostium of a vessel to be stented in part by contacting structures proximate the ostium with one or more rods associated with a deployment site locator. A stent is delivered to a desired stent location based upon on the so-determined position of the ostium and deployed. The deployment site locator is withdrawn from the patient. None of the cited references teach or suggest at least these limitations.

For example, the Office Action interprets the pedals 27 of the Lam stent 20 as being the “rods” of claim 28. However, the stent deployment method disclosed in Lam is entirely different from that of claim 28. In particular, Lam describes that stent 20 has a collapsible tubular body 24 and flaring portion 25 (that comprises the pedals 27 in some embodiments) extending distally from the tubular body 24. The stent 20 is deployed by first loading the tubular body 24/flaring portion 25 in a collapsed state onto a balloon 37 of a balloon catheter 23. The so-loaded balloon catheter 23 is then advanced into the patient’s circulatory system. *Lam*, col. 6, ll. 30-59. Based solely upon radiography, the stent is positioned within the diseased portion 31 of a bifurcated vessel 21. *Lam*, col. 6, l. 66 – col. 7, l. 2. Subsequently, the balloon 37 is expanded to seat the tubular body 24 within the diseased vessel 21, and the flaring portion 25/pedals 27 are expanded to “cap” the diseased portion 31. With the embodiment of FIG. 9 (and as relied upon by the Examiner), the stent 45 (unnumbered in the figure, but referenced in the text at col. 9, ll. 1-16) is comprised of a spring-like material, and a retaining sleeve 47 surround the entire stent 45 prior to deployment; as the retaining sleeve 47 is retracted, the flaring portion 25/pedals 27 expand as shown and as described above. Regardless, the flaring portion 25/pedals 27 engage the diseased portion 31. Importantly, however, this engagement is not used with the Lam methodology to

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“determine a position of the ostium” as otherwise required by claim 28. Rather, the flaring portion 25/diseased portion 31 engagement serves solely to cap or repair the diseased portion 31. Determining a desired position of the stent 20/45 is based only upon a visual estimate by the surgeon. That is to say, Lam does not teach or suggest “determining a position of the ostium by contacting structures proximate the ostium with at least one of the plurality of rods.” Rather, the flaring portion 25/pedals 27 are simply expanded/deployed at a best-guess location, and contact with the vessel 21/diseased portion 31 serves no purpose in determining desired positioning. This marked difference is further highlighted by the requirement of amended claim 28 whereby the deployment site locator is withdrawn from the patient. In contrast, the flaring portion 25/pedals 27 of Lam are an integral part of the stent 20/45 itself, and permanently remain in the vessel 21 following deployment. In that the Office Action views the flaring portion 25/pedals 27 of Lam as being the “deployment site locator” of claim 28, Lam further does not teach or suggest withdrawing the deployment site locator from the patient.

For at least the above reasons, amended claim 28 is allowable over Lam. Claims 29, 30, and 32-36 depend from claim 28 and thus, for at least these same reasons, are also allowable over Lam.

With respect to the rejection of claim 28 as being obvious over Brown in view of VanTassel, the Office Action references Figure 9 of Brown as disclosing “placement of a plurality of coils is used and a stent is placed a distance from the ostium.” From this explanation, it is assumed that the Office Action views the entrance to the aneurysm 102 of Brown as being “an ostium of a vessel to be stented” of claim 28. With this in mind, the method of Brown includes inserting a catheter into the patient’s vasculature and advancing the catheter to the site of the target aneurysm 100. In this regard, Brown simply describes that the distal tip of the catheter is positioned to be “abutting the entrance to the aneurysm 102.” *Brown, col. 8, ll. 45-47.* Brown provides no explanation as to how this abutting position is determined or accomplished. Regardless, Brown locates the entrance and positions the distal tip of the catheter relative to the aneurysm entrance 102 prior to deployment of the device 10. *Brown, col. 8, l. 49 – col. 9, l. 2.* In other words, to the extent the coils 60 of the device 10 are viewed as being analogous to the deployment site locator of claim 28, the coils 60 are not used to initially determine a position of

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the “ostium” as otherwise required by claim 28. Brown further describes that once deployed, fluoroscopy, ultrasound, or magnetic imaging techniques can be employed to evaluate placement of the device 10 relative to the aneurysm entrance 102. None of these methodologies teach or suggest the limitations of claim 28 whereby a position of the ostium is determined by contacting structures proximate the ostium with at least one of a plurality of rods (of the deployment site locator). Thus, even if the coils 60 could somehow be replaced with the membrane structure 40 (including the engagement members 508 or “rods” as identified in the Office Action) of VanTassel, the resultant method associated with the combined device would not change. Namely, the aneurysm entrance 102 would be located with the catheter distal tip prior to deployment of the modified device, and the alleged “rods” 508 would not be used to determine a position of the ostium by contacting structures of the ostium with one of the “rods” 508. For at least these reasons, then, claim 28 is allowable over Brown in view of VanTassel.

Even further, amended claim 28 recites that the deployment site locator is withdrawn from the patient. In direct contrast, Brown clearly requires that the retainer coils 60 of the device 10 remain within the patient as they accomplish the stated purpose of Brown of closing the aneurysm. The membrane 40/engagement members 508 of VanTassel must also remain within the patient. Thus, even if the retainer coils 60 of Brown were replaced by the membrane 40 of VanTassel, with the membrane/engagement members 508 serving as a “deployment site locator,” the combination fails to teach or suggest the requirement of amended claim 28 that the deployment site locator is withdrawn from the patient.

For at least the above reasons, amended claim 28 is allowable over Brown in view of VanTassel. Claims 29, 30, and 32-36 depend from claim 28 and thus, for at least these same reasons, are also allowable over Brown in view of VanTassel.

Newly Presented Claim

Newly presented claim 41 depends from claim 28 and is therefore allowable. In addition, claim 41 recites that the stent remains in the desired location upon withdrawing of the deployment site locator from the patient. Support for this language is found, for example, in

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FIGS. 8 and 19E. None of the cited references teach or suggest this limitation, such that claim 41 recites additionally allowable subject matter.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-12 and 14-41 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-12 and 14-41 are respectfully requested. No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

Any inquiry regarding this Amendment and Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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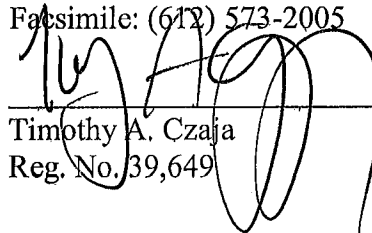
Respectfully submitted,

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